IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. PAUL R. McHUGH

TABLE OF CONTENTS

Plaintiffs respectfully submit this memorandum of law in support of their motion to exclude the expert testimony of Dr. Paul R. McHugh.[1]

STATEMENT OF THE CASE AND FACTS

Plaintiffs are current or former participants in the North Carolina State Health Plan for Teachers and State Employees (the "Health Plan"). North Carolina provides health coverage to its employees and their dependents through the Health Plan. The Plan denies coverage for the gender-affirming care that transgender people require because it contains sweeping exclusions of such care but covers the same kinds of treatments for cisgender employees who require them for other reasons. Defendants thus deny equal treatment to Plaintiffs because they are transgender.

INTRODUCTION

For 50 years, Dr. Paul R. McHugh has opposed the provision of gender-affirming care for transgender patients, because in his view they have a "disorder of assumption." Dr. McHugh opposes this care despite not having any direct experience providing care to transgender individuals or having conducted any original research or study on these issues. In fact, his longstanding opposition has remained immovable – "flat-footed," in his words – notwithstanding any new research published in the past half century. Nonetheless, the Plan Defendants attempt to proffer Dr. McHugh as an expert.

[1] Unless otherwise specified, all exhibits cited herein are attached to the contemporaneously filed Declaration of Omar Gonzalez-Pagan.

But Dr. McHugh is unqualified to serve as an expert in this case and his opinions should be excluded as irrelevant and/or unreliable under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. Dr. McHugh's views were formed 50 years ago despite his lack of direct experience and original study in these matters and have remained impervious to scientific development and scholarship since then. His opinions are also inadmissible under Rule 403 because any probative value they may have (and they have none) is substantially outweighed by the danger of unfair prejudice and confusion of the issues they would cause.

LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on a trial court, *Nease v. Ford Motor Co.*, 848 F.3d 219, 230 (4th Cir. 2017), to ensure that an expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597; *see also Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021). And "the importance of the gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283 (cleaned up).

"Where the admissibility of expert testimony is specifically questioned, Rule 702 and Daubert require that the district court make explicit findings, whether by written opinion or orally on the record, as to the challenged preconditions to admissibility." *Id.* "The proponent of the testimony must establish its admissibility by a preponderance of proof." *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F.Supp.3d 529, 537 (M.D.N.C. 2019) (quotation omitted), *aff'd*, 842 F.App'x 847 (4th Cir. 2021).

First, the court must determine whether the proposed expert is even qualified to render the proffered opinion, which requires examining the expert's professional qualifications and "full range of experience and training." *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012). If the purported expert is not qualified, the court should exclude the testimony. *See SMD Software, Inc. v. EMove, Inc.*, 945 F.Supp.2d 628, 639 (E.D.N.C. 2013).

Second, even if the expert is qualified, the court must consider the relevancy of the expert's testimony as it is "a precondition to admissibility." *Sardis*, 10 F.4th at 282. To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id.* at 281. "[I]f an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded." *Id.*

Third, the court must inquire if the opinion is based on a reliable foundation, focusing on "the principles and methodology" employed by the expert to assess whether it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Id.* at 281-82. In evaluating reliability, courts consider, among other things, whether: (1) the theory "can be and has been tested"; (2) has been "subjected to peer review and publication"; (3) "the known or potential rate of error"; and (4) "whether the technique is generally accepted in the scientific community." *Id.* at 281; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149-150 (1999). These factors are "neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199–200 (4th Cir. 2001) (citation omitted).

When an expert relies upon his experience and training, and not a specific methodology, the application of the *Daubert* factors is more limited. *See Freeman v. Case Corp.*, 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). In such cases, courts consider: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F.Supp.3d 579, 589 (E.D.N.C. 2015); *see also Nat'l Ass'n for Rational Sexual Offense Laws v. Stein*, No. 1:17CV53, 2021 WL 736375, at *3 (M.D.N.C. Feb. 25, 2021).

Finally, the Fourth Circuit has cautioned that although the trial court has "broad latitude" to determine reliability, it must still engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even rigorous cross-examination is not a substitute for the court's gatekeeping role. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017).

ARGUMENT

I. Dr. McHugh is not qualified to offer an expert opinion in this case.

An expert witness must possess the requisite "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993); *Wright v. United States*, 280 F.Supp.2d 472, 478 (M.D.N.C. 2003). If not qualified, the expert's testimony is unreliable. *Reliastar Life Ins. Co. v. Laschkewitsch*, No. 5:13-CV-210-BO, 2014 WL 1430729, at *1 (E.D.N.C. Apr. 14, 2014).

However, "qualifications alone do not suffice." *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999); *see also Patel ex rel. Patel v. Menard, Inc.*, No. 1:09-CV-0360-TWP-DML, 2011 WL 4738339, at *1 (S.D. Ind. Oct. 6, 2011). Even "[a] supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant under … *Daubert*." *Clark*, 192 F.3d at 759 n.5. To the contrary, "an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise." *Martinez v. Sakurai Graphic Sys. Corp.*, No. 04 C 1274, 2007 WL 2570362, at *2 (N.D. Ill. Aug. 30, 2007); *see also Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352, 1369 (11th Cir. 2014).

Despite his decades of experience in the field of psychiatry, Dr. McHugh is not qualified to render expert opinions on any of the issues at hand because he has no direct, particular, or specialized experience regarding gender dysphoria, its treatment, or transgender people more generally. Dr. McHugh's opinions are a perfect example of the circumstance where a party's proposed expert only provides "generalized knowledge" that risks creating more confusion rather than aiding a trier of fact. But, as we know, "[g]eneralized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge." *Martinez*, 2007 WL 2570362, at *2. "For example, no medical doctor is automatically an expert in every medical issue merely because he or she has graduated from medical school or has

achieved certification in a medical specialty." *O'Conner v. Commonwealth Edison Co.*, 807 F.Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994); *see also, e.g.*, *Hartke v. McKelway*, 526 F.Supp. 97, 100-101 (D.D.C. 1981). Such is the case here.

Dr. McHugh formed the opinions he espouses today nearly 50 years ago, without conducting any independent research at the time. Ex. A at 147:21-138:3. But those opinions are not based on any direct experience with transgender patients or people living with gender dysphoria, or any independent research that he has conducted he has conducted since then. The opposite. Dr. McHugh admits that he has not directly treated *any* transgender patients with gender dysphoria, Ex. A at 36:7-38:5, 39:1-10, 62:4-10, nor has he overseen any clinic providing hormonal or surgical care for transgender patients, *id.* at 58:17-59:5. He also has not conducted *any* original or peer-reviewed research about gender identity, transgender people, or gender dysphoria. Ex. A at 27:20-28:2, 30:7-31:9, 147:21-148:3; *see also United States v. Jacques*, 784 F.Supp.2d 59, 62 (D. Mass. 2011).

The extent of Dr. McHugh's direct, personal experience in his more than 50 years in the field of psychiatry is that he has briefly consulted, but not provided care, with 30-35 transgender persons or their families. Ex. A at 28:12-14, 30:3-6. Curiously, though, whenever he has referred one of those 30-35 persons or their families for actual care, Dr. McHugh has referred them to only one psychiatrist—Dr. Fred Berlin. *Id.* at 38:6-21. Dr. Berlin, however, works in Johns Hopkins's Sex and Gender Clinic, which partners with the Johns Hopkins Center for Transgender Health to provide gender-affirming care consistent with the standards of care set by the World Professional Association for

Transgender Health (WPATH), *id.* at 124:17-125:13; Ex. B at 261:2-262:6, and therefore provides care at odds with Dr. McHugh's outlier views.

And even though he purportedly calls for additional research on the effectiveness of gender-affirming treatment for gender dysphoria, it appears such calls are a pretense for Dr. McHugh's uninformed opposition to such care. Dr. McHugh has been aware of the provision of gender-affirming care since the 1970's, when he made up his mind to oppose this care but has yet to conduct a single study in the last 50 years. Ex. A at 155:6-10. As he testified, he joined Johns Hopkins with the "intention when [he] arrived in Baltimore in 1975 to help end" the provision of such care. *Id.* at 145:6-16.

Dr. McHugh has also not published any scientific, peer-reviewed literature on gender dysphoria or transgender people. Ex. A at 33:15-34:11. The one publication he has in a science journal that touches on this subject is not a scientific study but rather an opinion essay. *Id.* at 31:18-33:14; *see also* Ex. D.[2] But opinion pieces are not science. And a commentary piece from more than 25 years ago is not the type of creditable scientific literature that should inform an expert's opinions and testimony. More relevant, however, is whether Dr. McHugh's views have been peer-reviewed, vetted, and accepted in recent times. When asked if he had "sought to have his views regarding this matter, in the last few years, published in a peer-reviewed journal," Dr. McHugh testified he had asked the

[2] Commentary pieces in *Nature Medicine* are not necessarily peer reviewed. *See Content Types*, Nature Medicine, https://www.nature.com/nm/content (last visited Nov. 24, 2021).

New England Journal of Medicine if he could write something on these issues for them, but that the New England Journal of Medicine declined. Ex. B at 282:25-283:8.

Instead, Dr. McHugh bases his opinions solely on his review of literature and the few conversations he has had with people with whom he has provided limited consultations but not provided care. Ex. A at 28:3-11, 30:7-20.

Dr. McHugh testified: "I have not published an actual study. Right. I've reviewed studies, but I haven't made a study of my own, no." Ex. B. at 280:24-281:3. But the fact that Dr. McHugh has read about gender dysphoria and transgender people does not qualify him as an expert on these issues. "Expertise is not acquired through osmosis or accretion." *Veryzer v. Sec'y of Health & Hum. Servs.*, No. 06-0522V, 2010 WL 2507791, at *26 (Fed. Cl. June 15, 2010). That is precisely the sort of "generalized knowledge of a particular subject" that courts have rejected as a qualification under Rule 702. As with the disqualified expert in *Lebron* who "reached his opinion instead by relying on studies," it is simply not a sufficient qualification to serve as an expert witness. 772 F.3d at 1369.

The same holds true for the limited consultations he has had with people he has not provided any care. Dr. McHugh cannot speak of long-term effects of gender-confirming care when the few people he has consulted with received no care from him, let alone "long-term" care. Ex. A at 28:19-29:4, 36:21-37:9.

In sum, Dr. McHugh has no foundation of knowledge, skill, or experience necessary to serve as an expert on the diagnosis of gender dysphoria or the treatment paradigms for gender dysphoria. The fact that Dr. McHugh may be "an intelligent man," who is "well

read in the area," "has written a bit on the general topic," and "holds an opinion on the topic," "is not enough" to make him an expert on gender dysphoria and its treatment. *Jacques*, 784 F.Supp.2d at 62. Dr. McHugh's "degree of specialized knowledge is simply too thin to give his testimony the foundation needed to permit a [factfinder] to consider it." *Id.* Dr. McHugh is "not qualified by background, training, or expertise to opine" about any of the factual issues presented by this case, let alone the effects and propriety of a policy excluding coverage of medically necessary gender-confirming treatment for gender dysphoria. *Lebron*, 772 F.3d at 1369.

II. Dr. McHugh's opinions and testimony are not relevant to this case.

The "court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is a precondition to admissibility." *Sardis*, 10 F.4th at 282 (cleaned up). "[I]t is axiomatic that expert testimony which does not relate to any issue in the case is not relevant and non-helpful." *Knight v. Boehringer Ingelheim Pharms., Inc.*, 323 F.Supp.3d 837, 846 (S.D.W. Va. 2018) (cleaned up). In order to be relevant, an opinion needs to "fit" with the facts at issue. *Bourne v. E.I. DuPont de Nemours & Co.*, 85 F.App'x 964, 966 (4th Cir. 2004). "The test for relevance, or fit, considers whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F.Supp.3d 837, 846 (W.D.N.C. 2016) (cleaned up).

Dr. McHugh's opinions are not relevant to the issues in this case as they will not help the "trier of fact to understand the evidence or to determine a fact in issue." *Nease*, 848 F.3d at 229. Simply put, his opinions do not "fit" the facts at issue.

A. Dr. McHugh's opinions about "desistance" are irrelevant.

Take for example Dr. McHugh's opinions about purported "desistance" rates as a reason to question the provision of gender-confirming care. Dr. McHugh builds his ultimate opinion that "transgender patients should [] be encouraged to align their identity and presentation with the sex they were determined at birth," Ex. A at 201:18-202:12, upon the premise that "the evidence right now is to say if somebody says … their sex of opinion and the sex of their body are discordant -- discordant, they change and become concordant in 80 to 90 percent of the cases if they're allowed to go through puberty." *Id.* at 197:15-21. But not only are such opinions based on faulty propositions, they simply do not fit within the facts of this case.

For example, Dr. McHugh's opinion is based on antiquated studies showing that a majority of prepubertal children diagnosed with *gender identity disorder*—an outmoded diagnosis *distinct from gender dysphoria* with different diagnostic criteria—desisted from their gender nonconformity or cross-gender behavior. But the desistance studies to which he refers speak only to prepubertal youth who were diagnosed with *gender identity disorder* under prior versions of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders ("DSM"), and do not pertain to desistance in prepubertal youth diagnosed with *gender dysphoria* under the DSM-5. Ex. A at 196:12-20. A

distinction he does not understand (which further calls into question his purported expertise on the subject). *Id*. And in any event, the studies pertain to desistance among *prepubertal* children and not adolescents or adults. *Id.* at 194:3-11. But no hormonal or surgical care – i.e., the care at issue here – is recommended for or provided to *prepubertal* children, nor are any of the plaintiffs prepubertal children. Ex. B at 288:2-17.

Dr. McHugh's opinions regarding desistance are thus completely irrelevant.

B. Dr. McHugh's opinions regarding the validity and reliability of the DSM are irrelevant.

Dr. McHugh's opinions about the validity and reliability of the DSM, *see infra*, are also irrelevant. Dr. McHugh's opinions about the DSM are based on "a broader critique … in almost what its purpose is, that rather than serve as a guide to come up with a diagnosis based on observable phenomena or criteria, it should be more explanatory as to the nature and cause of a particular condition." Ex. A at 107:11-108:8. Dr. McHugh's critique *is not* based on the DSM's reliability to make diagnoses, i.e., to ascertain whether someone presenting with particular symptoms suffers from a particular condition. *Id.* at 99:3-100:16.

In any event, Dr. McHugh acknowledges that the World Health Organization's Internal Classification of Diseases (ICD) is a true classification system. Ex. A at 97:1-6. And the ICD defines gender incongruence as "a marked and persistent incongruence between the gender felt or experienced and the gender assigned at birth." *Id.* at 104:5-16; Ex. E.

C. Dr. McHugh's musings about the causes of gender dysphoria are irrelevant.

Dr. McHugh opines, without any evidence, that gender dysphoria *may be* caused by social contagion and social pressure. Ex. C at 13. While those hypotheses are completely unsupported, whether gender dysphoria is caused by social contagion or social pressure is irrelevant to the case at hand. It is undisputed that there are people that experience gender dysphoria, which necessitates medical treatment. Ex. A at 73:15-75:15, 203:14-204:14; *see also Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 594–95 (4th Cir. 2020).

* * *

The opinions expressed by Dr. McHugh are insufficiently tied to the facts of this case and should be excluded as irrelevant.

III. Dr. McHugh's opinions and testimony are unreliable.

An expert's testimony should only be admitted if it is sufficiently reliable. And "proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018). Here, Dr. McHugh's opinions fail all indicia of reliability. Dr. McHugh's proffered opinions are based on nothing more than rank speculation, "untested" theories, uncorroborated anecdotes, and assumptions that are obsolete, flawed, unethical, and expressed opinions based upon "unsettled science." What is more, some of his opinions are patently false.

A. Dr. McHugh's opinion encouraging reparative therapy is unreliable, widely rejected, unethical, and misleading.

The foundation of Dr. McHugh's opinions is that, according to him, transgender people are "disordered" because they suffer from a "disorder of assumption" or "overvalued idea." Ex. A at 129:5-12; Ex. B at 288:18-22. As such, Dr. McHugh's opinion is that transgender people with gender dysphoria be treated through therapy wherein they are led "to move from an idea that is unreal to the reality world that they need to live in and they should live in," by which he means that they should be coerced to live and identify according to "their natal sex." Ex. A at 204:20-206:5, 201:18-202:7. But such opinion is unreliable, widely rejected, and unethical.

Dr. McHugh cites to no study in support of this proposition, instead, "relying on, primarily, common sense." Ex. B at 305:17-21. In fact, from Dr. McHugh's point of view, it "is [his] opinion," and the burden of proof is on everyone else to change his opinion. *Id.* at 305:22-306:10. But that is not how it works in court, where a proposed expert's "*ipse dixit* … cannot satisfy Rule 702." *Sardis*, 10 F.4th at 289. Nor does Dr. McHugh's appeal to untestable "common sense" satisfy Rule 702's reliability requirement. *See Fedor v. Freightliner, Inc.*, 193 F.Supp.2d 820, 832 (E.D. Pa. 2002) ("Generalized common sense does not rise to the level of expert opinion solely because it is offered by someone with an academic pedigree.").

But "[f]or many years, mental health practitioners attempted to convert transgender people's gender identity to conform with their sex assigned at birth, which did not alleviate dysphoria, but rather caused shame and psychological pain." *Grimm*, 972 F.3d at 595. As

such, the American Psychological Association opposes gender identity change efforts because "scientific evidence and clinical experience indicate that [these efforts] put individuals at significant risk of harm" and "have not been shown to alleviate or resolve gender dysphoria." Ex. F; *see also* Ex. A at 210:19-213:21. So does the American Psychiatric Association. *Id.* at 206:6-20.

As a result, gender identity change efforts are considered to be unethical, and have been widely rejected by the medical and scientific community. Ex. A at 214:1-14; Ex. G at 12-16; *see also King v. Governor of the State of New Jersey*, 767 F.3d 216, 221–22 (3d Cir. 2014); *Pickup v. Brown*, 740 F.3d 1208, 1223–24 (9th Cir. 2014).

B. Dr. McHugh's views are at odds with the relevant scientific and medical communities.

General acceptance in the relevant scientific community is an important element to the reliability inquiry. *Nease*, 848 F.3d at 229. Not only is widespread acceptance an important factor in assessing the reliability of an expert's opinions, but the fact that a known theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594. Here, Dr. McHugh's opinions about the effectiveness and propriety of gender-affirming care are way outside the mainstream of medical and scientific opinion and have been explicitly rejected by the relevant scientific and medical communities.

Dr. McHugh opines that gender-affirming "treatments – hormones and surgery – for gender dysphoria and 'transitioning' remain unproven and have thus not been accepted by the relevant scientific communities." Ex. C at 14. Not true. It is the official, consensus,

evidence-based position of the National Academies of Science, Engineering, and Medicine that, "[a] major success of these guidelines has been identifying evidence and establishing expert consensus that gender-affirming care is medically necessary and, further, that withholding this care is not a neutral option." Ex. G at 12-10.[3] Indeed, "[a] number of professional medical organizations have joined WPATH in recognizing that gender affirming care is medically necessary for transgender people." *Id*. This includes, among others, the American Medical Association, American Psychiatric Association, American Psychological Association, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, the Endocrine Society, the Pediatric Endocrine Society, and Dr. McHugh's own employer, Johns Hopkins University. Ex. B at 247:22-263:14.

Binding and recent circuit precedent recognizes the provision of gender-confirming care, consistent with the WPATH Standards of Care, to "represent the consensus approach of the medical and mental health community," and to "have been recognized by various courts, including [the Fourth Circuit], as the authoritative standards of care." *Grimm*, 972 F.3d at 595. In fact, "[t]here are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups." *Id.* at 595-596.

[3] Exhibit G, a report of the National Academies, is self-authenticating as a publication issued by a public authority, Fed. R. Evid. 902(5), and is appropriate for judicial notice, *United States v. Doe*, 962 F.3d 139, 147 n.6 (4th Cir. 2020).

Just this year, another federal district court found as much when it enjoined Arkansas' state law seeking to ban gender-confirming treatment for minors. *See Brandt v. Rutledge*, No. 4:21-CV-00450-JM, 2021 WL 3292057 (E.D. Ark. Aug. 2, 2021). In doing so, the court explicitly found that: (a) "Gender-affirming treatment is *supported by medical evidence* that has been *subject to rigorous study*;" and (b) "*Every major expert medical association* recognizes that gender-affirming care for transgender minors may be *medically appropriate and necessary* to improve the physical and mental health of transgender people." *Id.* at *4 (emphasis added).

On the other hand, Dr. McHugh's view that affirming a transgender person's identity is "affirming the patient's misdirection," Ex. A at 64:19-65:6, has been soundly rejected by medical and scientific community.

Lastly, aside from the fact that his opinion is wildly at odds with that of the relevant medical and scientific communities, the fact that Dr. McHugh omitted key information from his report undermines his reliability and illustrates that his opinions are more likely to mislead than to enlighten. Dr. McHugh was aware that the positions taken by most major medical organizations and his own employer were contrary to his own but failed to disclose or account for that information in his report just because he disagreed with them. Ex. B at 257:6-17. While the factual basis of an expert opinion usually goes to credibility, "it is possible for an experts' omission of articles to render his or her opinion inadmissible on reliability grounds." *Huggins v. Stryker Corp.*, 932 F.Supp.2d 972, 994 (D. Minn. 2013). Such is the case here where Dr. McHugh omits key information, or worse,

misrepresents facts that if properly disclosed would contradict his opinions. In such circumstances, the "potential to mislead" rather "than to enlighten" is too great. *In re Lipitor*, 892 F.3d at 632.

C. Dr. McHugh's opinions are based on speculation and untested theories.

Dr. McHugh's opinions are based on speculation and untested theories; theories that neither he nor others have tested or studied. For example, several of Dr. McHugh's opinions are based on "unknown number[s]" of patients with gender dysphoria purportedly (a) suffering from other conditions distorting their judgment or (b) being "heavily influenced and/or manipulated by a source of social contagion." Ex. C at 13. But Dr. McHugh was unable to identify a single scientific, peer-reviewed source as to the former, Ex. B at 293:22-295:8, and only identified one source that proposed the latter merely as a hypothesis, *id.* at 298:15-300:5.[4] As such, "there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

"While hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination." *Dunn v. Sandoz Pharms. Corp.*, 275 F.Supp.2d 672, 684 (M.D.N.C. 2003). Indeed, such "speculation is unreliable evidence and is inadmissible." *Id.*; *see also Sardis*, 10 F.4th at 291.

[4] The only study to have looked at this hypothesis found no support for the hypothesis. Ex. H.

In sum, Dr. McHugh's opinions based on "unsupported speculation" should be rejected. *Daubert* 509 U.S. at 589-590.

D. Dr. McHugh's opinions regarding care in other countries are unreliable.

In support for his opinions, Dr. McHugh refers to purported "national research reviews in England, Sweden, and Finland." Ex. C at 10. But it is hard to ascertain the reliability, if any, of these purported national reviews. For one, Dr. McHugh provides no citations to any these purported reviews in his report. For another, Dr. McHugh does not know if the "national reviews" in England and Finland were peer-reviewed or published in scientific journal. *See, e.g.*, Ex. B at 300:19-301:10 (England), 302:20-303:8 (Finland). He also confused a scientific study by some researchers in Sweden for a "national review," a distinction he acknowledged at his deposition. *Id.* at 301:12-20 (confusing the Dhejne, et al. 2011 study with Swedish national review).[5]

In addition, Dr. McHugh acknowledged he did not disclose that each of the countries to which he refers have nationalized healthcare systems that provide and cover gender-confirming medical treatment for adolescents and adults with gender dysphoria. *Id.* at 304:10-305:7.

[5] In any event, Dr. McHugh misrepresents the Dhejne, et al. study which only shows that post-operative transgender patients have higher rates of suicidality when compared to the *population at large*. Ex. A 157:10-160:16, 163:6-164:15; *see also* Doc. 181-1 (Ex. 25(a) at ¶ 83 (Ettner); Ex. 26(a) at ¶ 81 (Olson-Kennedy); Ex. 24(b) at ¶ 28 (Schechter Rebuttal)).

E. Dr. McHugh's opinions regarding the reliability of the DSM are unreliable and misleading.

Dr. McHugh criticizes the reliability and validity of the DSM to make diagnoses, which consequently fuels his opinions regarding gender dysphoria. But not only are these opinions irrelevant (see above), they are also unreliable.

Courts have routinely recognized the DSM as a reliable and widely accepted authority on mental disorder diagnoses. *See United States v. Wooden*, 693 F.3d 440, 452 n.4 (4th Cir. 2012) ("The DSM is widely recognized as the authoritative reference used in diagnosing mental disorders." (cleaned up)); *see also Acevedo Granados v. Garland*, 992 F.3d 755, 760 n.1 (9th Cir. 2021); *Kim v. Hartford Life Ins. Co.*, 748 F.App'x 371, 374 (2d Cir. 2018); *Rasho v. Elyea*, 856 F.3d 469, 472 (7th Cir. 2017); *Young v. Murphy*, 615 F.3d 59, 61 (1st Cir. 2010); *Vanieken-Ryals v. Off. of Pers. Mgmt.*, 508 F.3d 1034, 1037 (Fed. Cir. 2007).

In addition, Dr. McHugh criticizes the DSM as "not based on evidence-seeking scientific methodologies," Ex. A at 105:2-6, even though he acknowledges that the revision of the DSM involves research evaluation, publication of whitepapers, peer-reviewed articles, and scientific conferences, *id.* at 105:16-106:18, something he did not disclose. Yet, at his deposition, Dr. McHugh acknowledged the "DSM does use scientific information to encourage its own reliability studies." *Id.* at 107:3-5.

Dr. McHugh refers to the decision of the National Institute of Mental Health (NIMH) to "reorient[] its research away from DSM categories" as support for his view of the DSM as "insufficiently reliable." Ex. C at 8. However, Dr. McHugh failed to disclose

that this was done as part of the NIMH's Research Domain Criteria project's "long-term goal to understand mental illness as disorders of brain structure and function," and that the NIMH considers the DSM, along with the ICD, to "represent[] the best information currently available for clinical diagnosis of mental disorders" and "that the DSM is the key resource for delivering the best available care" as well as "the main contemporary consensus standard for how mental disorders are diagnosed and treated." Ex. A at 116:10-122:11. The fact that Dr. McHugh misrepresented or omitted such information central to his opinions calls into question the reliability of his opinions.

Lastly, Dr. McHugh has authored and advocated for an alternative to the DSM since the 1980's, but as he admits, his alternative *is not* widely accepted by the relevant scientific and medical community. *Id.* at 108:9-110:14. And the fact that a known theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594.

F. Dr. McHugh's opinions rely on his own unreliable and non-scientific publications.

In his report, Dr. McHugh primarily relies on his own non-scientific, non-peer-reviewed publications as support for his own opinions. *See generally* Ex. C. But such publications lack any indicia of reliability. Really, they are all just opinion articles by Dr. McHugh, not actual studies. Ex. B at 280:24-281:3.

Take for example Dr. McHugh's two publications in *The New Atlantis*. *The New Atlantis* is neither a peer-reviewed nor a scientific publication, but rather "an ordinary journal for the public." Ex. B at 264:1-19. The same holds true for his other publications

on this area. *Id.* at 276:19-277:19, 279:20-280:7, 280:15-23; Ex. A at 21:17-22:4. Indeed, Dr. McHugh acknowledges these are all just articles of opinion, "as you might find in 'The Atlantic' or in 'The New Republic' or in 'The New Yorker.'" Ex. B at 266:3-5, 277:16-19.

As such, as a court that reviewed Dr. McHugh's "Sexuality and Gender" article noted, they do not carry "any … indicia of reliability." *Evancho v. Pine-Richland Sch. Dist.*, 237 F.Supp.3d 267, 278 n.12 (W.D. Pa. 2017). To the contrary, Dr. McHugh's publications have been publicly denounced by hundreds of scientists and medical professionals, which Dr. McHugh acknowledges are "part of the relevant scientific community," as not representing the "prevailing expert consensus opinion about sexual orientation or gender identity related research or clinical care." Ex. I; Ex. B. at 266:21-267:22.

Similarly, colleagues at Johns Hopkins have publicly denounced Dr. McHugh's publications as "mischaracteriz[ing] the current state of the science on sexuality and gender." *Id.* at 268:9-269:15; Ex. J. So did Dr. Dean Hamer, a renowned geneticist who Dr. McHugh describes as a "distinguished person" and "certainly relevant" part of the scientific community. Ex. B at 269:20-270:8. Indeed, Dr. Hamer has described the opinions expressed by Dr. McHugh in his non-scientific opinion pieces as "pure balderdash" that engage in "data cherry-picking" and "jump to [] conclusion[s], with no supporting evidence or calculations whatsoever," all for the "not-too-subtle implication … that LGBT people are intrinsically defective, and that no amount of legal or societal

acceptance will ever fix them." Dean Hamer, *New 'Scientific' Study on Sexuality, Gender Is Neither New nor Scientific*, The Advocate (Aug. 29, 2016, 2:21 PM), https://bit.ly/3xlpT2x.

In sum, Dr. McHugh's opinions should be excluded because they mostly rely on his own non-scientific opinion pieces that are themselves unreliable and have been resoundingly denounced by scientific community as misleading, at best.

G. Dr. McHugh's extreme opinions are unreliable because they are tainted with bias and prejudice.

Dr. McHugh's opinions are unreliable because they are tainted by bias and prejudice. Even Dr. McHugh's own co-authors, like Dr. Lawrence Mayer, have described his views regarding transgender people as "extreme" and "mean-spirited." Ex. B at 274:4-19. Dr. Mayer has described Dr. McHugh's statements regarding LGBTQ people as "anti-gay, anti-transgender." *Id.*

But one need not just rely on the views of Dr. McHugh's colleagues. One need only look at Dr. McHugh's writings and testimony to see that it is permeated with bias and prejudice. Take the following statements by Dr. McHugh:

- Stating that transgender people "are disordered" and "suffer from an overvalued idea," Ex. B at 288:18-21, 297:5-6;
- Describing transgender women as "caricatures of women," Ex. A at 143:3-14; Ex. B at 278:1:22;
- Referring to transgender people as "gender pretenders," Ex. B at 274:4-19, 276:1-14;

- Asserting that transgender people "have a disorder of assumption," Ex. A at 129:10-12;
- Declaring that "conditioning children into believing that a lifetime of impersonating someone of the opposite sex achievable only from chemical and surgical interventions is a form of child abuse," Ex. B. at 286:9-14; and
- Speaking of gender-affirming treatment as resulting in the "ghastliness of the mutilated body," Ex. A at 149:15-16.

Such rhetoric on its own illustrates how Dr. McHugh's opinions, which have been ossified since the 1970's, are so permeated by negative attitudes at best, and bias and prejudice at worst, as to render them completely unreliable. They also illustrate how Dr. McHugh's opinions have "a greater potential to mislead than to enlighten" and thus "should be excluded." *In re Lipitor*, 892 F.3d at 632. Indeed, Dr. McHugh testified that he is "quite flat-footed about this." Ex. B at 287:17-18.

And though Dr. McHugh's opinions illustrate bias regardless of motivation, it is also relevant that most of his publications on these issues are in religiously affiliated publications. For example, *The New Atlantis* was published by the Ethics and Public Policy Center, which represents itself as an "institute dedicated to applying the Judeo-Christian moral tradition to critical issues of public policy," which Dr. McHugh knew. Ex. B at 264:20-265:11. And Dr. McHugh's article "Surgical Sex" was published in *First Things*, a publication of the Institute on Religion and Public Life, *id.* at 276:19-277:9, and which he began by making reference to the "Serenity Prayer." *Id.* at 278:23-279:1.

It thus appears that Dr. McHugh's opinions are colored by his own private moral and religious beliefs, which is "critical information," the Court should consider as it "appropriately draw inferences about [Dr. McHugh's] reliability." *State v. Heinz*, 485 A.2d 1321, 1328 (Conn. App. 1984). To be clear, Dr. McHugh is entitled to hold his own private views, and Plaintiffs do not seek to impugn or malign them. However, to the extent Dr. McHugh's personal views have influenced his purported expert opinions—indeed, they appear to be a motivating factor—that is something the Court must be aware of and should consider as it assesses the reliability of his testimony.

Dr. McHugh's opinions should be excluded based on his extreme and negative rhetoric towards transgender people alone, which renders his opinions as unreliable.

* * *

In sum, Dr. McHugh's opinions fail to meet the most basic indicia of reliability and his opinions and testimony should be excluded as unreliable.

IV. Dr. McHugh's opinions lack probative value and are therefore inadmissible under Rule 403.

Finally, the Court should exclude Dr. McHugh's opinions because their introduction will result in unfair prejudice, confusion of the issues, or in misleading testimony. Fed. R. Evid. 403. Dr. McHugh offers no opinions relevant to the issues in this case, and, in any event, the opinions he offers are unfounded, speculative, and unreliable. The testimony would also result in prejudice, as the testimony seeks to sow confusion about the propriety of gender-confirming care based on speculation, irrelevant, misleading, or biased opinions.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. McHugh's report, opinions, and testimony in full.

Dated this 2nd day of February, 2022.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 6,250 words as indicated by Microsoft Word, the program used to prepare this document.

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CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

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